

# PSJ3

# Exhibit 391





## **Q & A on Industry Compliance Guidelines**

**Q. Why did HDMA develop these Guidelines?**

**Q. How will the supply chain be affected by implementation of these Guidelines?**

**Q. How will following the Guidelines enhance security?**

**Q. Do the Guidelines go above and beyond the requirements of current law?**

Yes. Current law requires distributors to report suspicious orders upon discovery. These guidelines provide an action plan that distributors can use to effectively ensure compliance with this requirement. That said, some of the recommendations in the guidelines that are not required by law. For instance, there is no legal requirement for distributors to audit and investigate new customers prior to opening an account. There is also no requirement for distributors to set order limits, or thresholds, for controlled substances. HDMA members have agreed to these extra measures in order to help DEA and other law enforcement officials combat the growing problem of illegal prescription medicine abuse.

**Q. Can these Guidelines be implemented by all distributors, large and small?**

Yes. The Guidelines were developed by the member companies of HDMA, which include large, regional and family-owned businesses.

**Q. How will HDMA enforce these Guidelines, and how can you be sure all your members follow them?**

**Q. If members follow these Guidelines, does that mean that they are in compliance with DEA requirements?**

**Q. How will these Guidelines affect the supply of medicines? If a distributor stops an order, doesn't that mean that pharmacies won't be able to get the medicines they need to serve patients?**

**Q. What about pain clinics? Won't these Guidelines automatically put pain treatment facilities in the category of 'suspicious?'**

**Q. What are the order thresholds? Why aren't these made public? How will pharmacists know how much they can order at one time?**

**Q. If a member stops a pharmacy order, how can a pharmacist appeal that decision and get their order when they know they put in a legitimate request for controlled substances?**

**Q. Will you notify pharmacists in advance if you decide not to ship an order?**

**Q. Will these Guidelines stop the DEA from closing distribution centers? Isn't that why your members developed them?**

**Q. Why do we need these Guidelines?**

**Q. Aren't these Guidelines overly broad? What qualifies a distributor to decide who's a legitimate pharmacy and who isn't?**

**Q. What happens when a distributor reports a suspicious order? Does DEA investigate? Compare the report to those coming in from other distributors? Revoke the pharmacy's license?**

**Q. What happens when a distributor determines that an order is suspicious, undertakes an investigation, and then deems the order to be OK. Do they report those results to DEA?**

**Q. What else are distributors doing to further secure controlled substances in the supply chain?**



## **Q & A on Uniform Federal Pedigree**

Pedigree is just one part of a comprehensive anti-counterfeiting strategy that must involve manufacturers, distributors and pharmacies. HDMA and the nation's primary healthcare distributors strongly support:

- Stricter licensing standards to ensure consistency across the 50 states;
- Tougher regulation, stronger law enforcement and harsher criminal penalties for the crime of counterfeiting medicine;
- The adoption of current and emerging track and trace technologies;
- The development of new research and best business processes in the supply chain.

### **Q. I've heard the supply chain is already safe. Why do we need these additional measures?**

The U.S. healthcare supply chain is one of the most sophisticated in the world, providing a strong system for the safe and efficient delivery of medicines to patients nationwide. Manufacturers, distributors and pharmacies work daily to help ensure that patients receive the right medicine, at the right place, at the right time. These companies share a primary responsibility to continuously monitor, protect and enhance this secure system against increasingly sophisticated criminals who may try to introduce counterfeit or diverted drugs into the legitimate chain.

Supply chain partners work together to continuously explore and implement innovative business, policy and technology solutions that create additional levels of safety, efficiency and value for the benefit of patients. HDMA believes that current and emerging technologies that can track and trace prescription medicines from the manufacturer, to the distributor, to the pharmacy, hold the most promise for safety advances in the supply chain, increased efficiencies and overall streamlined operations.

### **Q. Have you discussed these Guidelines with other organizations? What was their reaction?**

Yes, HDMA has discussed the proposal with members of the Rx SafeTrack group, including PhRMA, NACDS, NCPA, BIO and GPhA.

For their specific opinion, it would be best to contact these organizations directly.

### **Q. How much will it cost companies to implement these recommendations?**

Each company's investment will vary, depending on their position in the healthcare supply chain, the systems they choose to deploy, the number of products that must be tracked-and-traced, etc. The proposal does assume that all segments of the supply chain will need to make some level of investment in enhancing the safety and security of the system, on behalf of patients. However, HDMA believes that in addition to the safety benefits, track-and-trace systems also hold the most promise for increasing efficiencies, streamlining operations, enhancing value and eliminating waste, which may offset some of the costs of deployment.

Moving forward, HDMA and the Center for Healthcare Supply Chain Research plan to quantify some of these costs and provide supply chain partners with additional information they can use to help inform their track-and-trace adoption plans.



**Q & A on Uniform Federal Pedigree**

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**About HDMA**

The Healthcare Distribution Management Association (HDMA) and its members are committed to patient safety by delivering life-saving health products and services through a secure and efficient healthcare distribution system. These primary, full-service healthcare distributors are responsible for ensuring that billions of units of medication are safely delivered -- to tens of thousands of retail pharmacies, nursing homes, clinics and providers -- in all 50 states. HDMA and its members are the vital link in the healthcare system that is responsible for medicine safety, quality, integrity and availability in the marketplace. Through leadership on public policy and industry best practices, HDMA and its members focus on providing value, removing costs and developing innovative solutions to deliver care safely and effectively. For more information, please visit [www.HealthcareDistribution.org](http://www.HealthcareDistribution.org).